International has experience; and, (c) SRS International's stated assumptions as to clinical trial design and experience with cost factors for such clinical trials. Both Histogenics Corporation and SRS International Corporation agree that: (1) SRS International will use its best efforts to provide needed laboratory and clinical studies at the lowest bid price from vendors which is consistent with quality and timeliness of performance; (2) that SRS International will not let any non-clinical or clinical study without Histogenics Corporation being first provided for its own review with the bids obtained by SRS International Corporation and Histogenics Corporation's approval of SRS International's selection of appropriate non-clinical and clinical study sites; (3) that as may be required by FDA requests or by changes in the study design assumptions set forth herein that the associated costs for non-clinical laboratory studies, clinical studies, and certain portions of SRS International's fees associated with the management, monitoring, evaluation, and reporting of same may change; provided however, that no change order to the costs above estimated shall be made without Histogenics Corporations' prior review and approval, which approval shall not unreasonably be withheld unless Histogenics Corporation decides as a result to revoke this Task Order pursuant to the revocation provision of the Master Consulting Agreement.

Contingent Program if Device Persists 28-Days or Greater:

As specified in the program cost proposal submitted to Histogenics Corporation and dated November 16, 2000 and as amended per discussions between Histogenics Corporation and SRS International Corporation the Contingent Program cost for the above stated Scope of Work (exclusive of travel) is estimated as:

Contingent Studies to be Completed Prior to IDE, Only if Required

SRS International fees for Contingent Program	$ 31,500.00
Non-clinical Laboratory fees for Base Program	$ 210,000.00
Clinical Site fees for Base Program	$ 0.00
Contingent Program Total 1	$ 241,500.00

The details of the above-stated Contingent Program cost estimates are provided in Attachment No. 2 to this Task Order which is incorporated herein by reference. This cost estimate figure is provided as a good faith estimate based on: (a) SRS Internationals' experience with data requirements and approval issues for medical implant devices; and, (b) SRS International's preliminary cost discussions with various laboratory service vendors with whom SRS International has experience. There are no clinical studies or costs associated with the above-stated Contingent Program. This Contingent Program is expected to be triggered only in the event that the TES tissue implant persists at the site of implantation greater than or equal to 28-days post-implantation (in which case it is typically considered to be a permanent implant by FDA). Both Histogenics Corporation and SRS International Corporation agree that: (1) SRS International will use its best efforts to

provide needed laboratory studies at the lowest bid price from vendors which is consistent with quality and timeliness of performance; (2) that SRS International will not let any non-clinical study without Histogenics Corporation being first provided for its own review the bids obtained by SRS International Corporation and Histogenics Corporation's approval of SRS International's selection of appropriate non-clinical study sites; (3) that as may be required by FDA requests or by changes in the study design assumptions set forth herein that the associated costs for non-clinical laboratory studies and certain portions of SRS International's fees associated with the management, monitoring, evaluation, and reporting of same may change; provided however, that no change order to the costs above estimated shall be made without Histogenics Corporations' prior review and approval, which approval shall not unreasonably be withheld unless Histogenics Corporation decides as a result to revoke this Task Order pursuant to the revocation provision of the Master Consulting Agreement.

The above estimates do not include travel costs. SRS International Corporation will advise Histogenics Corporation that a certain number of trips will be needed and negotiate a budget for travel on this basis. As an example of SRS's approach to travel costs, a pilot clinical study with one center located somewhere between New England and Florida, one would estimate a maximum of 6 visits as day-trips. At a reasonable $500 per airfare, this is $3,000 in air travel for the pilot study.

TIME FRAME FOR COMPLETION:

SRS International will complete the Scope of Work on the following schedule:

As per the time frame estimates provided on Attachment No. 1 to this Task Order, which is incorporated herein by reference. The "clock" for these time frames will commence as of the execution of this Task Order by Histogenics Corporation and receipt by SRS International Corporation of the start-up payment called for hereunder.

Both Histogenics Corporation and SRS International Corporation agree that SRS International will use its best efforts to adhere to the stated time frame estimates; provided that, Histogenics Corporation responds timely to SRS information queries and requests for decisions and that factors outside of SRS International Corporation's reasonable control do not occur. As may be required due to Histogenics Corporations' own needs, tardiness in response to SRS International requests, and/or factors outside of SRS International's reasonable control these time frames may be reasonably adjusted by mutual consent; provided however, that no change order to the time frames above estimated shall be made without Histogenics Corporations' prior review and approval, which approval shall not unreasonably be withheld unless Histogenics Corporation decides as a result to revoke this Task Order pursuant to the revocation provision of the Master Consulting Agreement.

CONDITIONS OF COMPENSATION:

Histogenics Corporation agrees to the following payment schedule in connection with this Task Order:

Base Program 1 (through Phase I Clinical Study)

Due Date	% of Cost	Payment Total
SRS Fees –		
On Contract Execution[1]	22.19%	$ 39,340.00
On Placing Standard Biocompatibility Tests and 28-Day Implant Biocompatibility Study in Rabbits[2]	2.41%	$ 4,275.00
On Communicating with FDA to set up pre-IDE Meeting[3]	7.05%	$ 12,504.00
On pre-IDE meeting[4]	14.10%	$ 25,000.00
On Reporting Standard Biocompatibility Tests and 28-Day Implant Biocompatibility Study in Rabbits[2]	2.41%	$ 4,275.00
On IDE Submission[4]	14.10%	$ 25,000.00
On IDE Approval[5]	9.32%	$ 16,520.00
On Clinical Trial Initiation[6]	8.52%	$ 15,107.85

[1] Covers: detailed review of TES system, general consultation costs, request for assignment of review component at FDA, follow-up on request for assignment, and consultations on pig study design.

[2] Cover 50% of associated estimated SRS fees

[3] Covers fees for pre-IDE meeting preparation and pre-IDE meeting

[4] Covers 50% of IDE preparation fees

[5] Covers IDE follow-up, pre-study IRB and investigator interaction, and other pre-study activity

On 50% enrollment in Phase I clinical trial[7]	5.68%	$ 10,071.90
On 100% enrollment in Phase I clinical trial[7]	5.68%	$ 10,071.90
On Draft Phase I Report[8]	4.26%	$ 7,553.92
On Final Phase I Report[8]	4.26%	$ 7,553.93
Totals	100.00%	$177,273.50

Non-clinical laboratory fees -

Per study placed, normally as 50% at placement, and 50% on report, therefore estimated at -

On Placing Standard Biocompatibility Tests and 28-Day Implant Biocompatibility Study in Rabbits	$ 28,500.00
On Reporting Standard Biocompatibility Tests and 28-Day Implant Biocompatibility Study in Rabbits	$ 28,500.00

Clinical Site fees -

Typically 40% on placement, 20% on 50% enrollment, 20% on 100% enrollment and 20% on study completion / site closure with all data queries resolved. Therefore, estimated at -

On study placement	$ 51,800
On 50% enrollment	$ 25,900
On 100% enrollment	$ 25,900
On close out and query resolution	$ 25,900

Payments are to be due and payable as specified in the Master Consulting Agreement for progress and/or milestone payments.

[6] Covers 30% of SRS fees for clinical trial
[7] Covers 20% of SRS fees for clinical trial
[8] Covers 15% of SRS fees for clinical trial

Base Program 2 (Phase II/III Clinical Study through PMA Approval)

Due Date	% of Cost	Payment Total
SRS Fees –		
On Filing IDE Supplement to Start Phase II/III Studies[9]	5.01%	$ 29,760.00
On Clinical Trial Initiation[10]	17.57%	$104,444.43
On 50% enrollment in Phase II/III clinical trial[11]	11.71%	$ 69,629.62
On IDE Annual Report No. 1	0.84%	$ 5,000.00
On 100% enrollment in Phase II/III clinical trial[11]	11.71%	$ 69,629.62
On IDE Annual Report No. 2 (if needed)	0.84%	$ 5,000.00
On Draft Phase II/III Report[12]	8.78%	$ 52,222.22
On initiation of pre-PMA meeting activity	1.92%	$ 11,424.00
On completion of pre-PMA meeting[13]	12.61%	$ 75,000.00
On Final Phase II/III Report[12]	8.78%	$ 52,222.22
On submission of PMA[14]	6.91%	$ 41,070.00
On setting of date for Advisory Panel meeting	6.40%	$ 38,080.00

[9] Covers: general consultation costs & supplement preparation
[10] Covers 30% of SRS fees for clinical trial
[11] Covers 20% of SRS fees for clinical trial
[12] Covers 15% of SRS fees for clinical trial
[13] Covers 50% of PMA preparation fees
[14] Covers 25% of PMA preparation fees plus 50% of PMA follow-up fees

On approval of PMA[15]	6.91%	$ 41,070.00
Totals	100.00%	$594,552.13

Clinical Site fees -

Typically 40% on placement, 20% on 50% enrollment, 20% on 100% enrollment and 20% on study completion / site closure with all data queries resolved. Therefore, estimated at –

On study placement	$600,000.00
On 50% enrollment	$300,000.00
On 100% enrollment	$300,000.00
On close out and query resolution	$300,000.00

Payments are to be due and payable as specified in the Master Consulting Agreement for progress and/or milestone payments.

Contingent Program (if implemented)

Due Date	% of Cost	Payment Total
SRS Fees –		
On Placing Studies	50%	$ 15,750.00
On Reporting Studies	50%	$ 15,750.00
Totals	100%	$ 31,500.00

Non-clinical laboratory fees –

Per study placed, normally as 50% at placement, and 50% on report, therefore estimated at –

On Placing Studies	$105,000.00
On Reporting Studies	$105,000.00

[15] Covers 25% of PMA preparation fees plus 50% of PMA follow-up fees

Payments are to be due and payable as specified in the Master Consulting Agreement for progress and/or milestone payments.

APPROVALS:

4-5-01

John A. Todhunter, Ph.D.
DABT, DABFE, FAIC, RAC
President,
SRS International Corporation

Date

7-11-01

Laurence J.B. Tarrant, Ph.D.
President,
Histogenics Corporation

Date

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WESTERN DIVISION

CIVIL ACTION NO.

HISTOGENICS CORPORATION,
Plaintiff

vs.

SRS INTERNATIONAL CORPORATION,
Defendant

AFFIDAVIT OF ATTORNEY
L. JEFFREY MEEHAN

I, L. Jeffrey Meehan, depose and say that I have been retained by Histogenics Corporation ("Histogenics") to serve as its counsel in its dispute with SRS International Corporation ("SRS"). In accordance with Article 10, "Dispute Resolution" of the Master Agreement between Histogenics and SRS (Exhibit B), I filed a Demand for Arbitration/ Mediation with the Commercial Division of the American Arbitration Association on October 9, 2003. On October 27, 2003, my submission together with my client's entry fee, was returned to me by the American Arbitration Association. Upon inquiry, I was informed that the Association could not obtain jurisdiction over the dispute as the Master Services Agreement did not specify it as the forum for dispute resolution and because, upon inquiry, SRS's counsel, Paul D. Pellegrin, refused to agree to submit the matter to the American Arbitration Association for mediation or binding arbitration. On October 31, 2003, I wrote to Attorney Pellegrin requesting that SRS agree to submit the instant dispute to arbitration/mediation before the American Arbitration Association. A copy of that letter is appended as Exhibit F. No response was ever forthcoming from Attorney Pellegrin or SRS. Suit was thereafter filed by SRS against Histogenics and

others in the Superior Court of the District of Columbia, Docket Number 03-0010153 and removed to the United States District Court for the District of Columbia where it was dismissed on August 16, 2004.

Signed under the penalties of perjury this 16th day of September, 2004.

L. Jeffrey Meehan

DOHERTY, WALLACE, PILLSBURY AND MURPHY, P.C.

ATTORNEYS AT LAW

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(1919-1996)
ROBERT E. MURPHY
(1919-2003)

† REGISTERED PATENT ATTORNEY
* ALSO ADMITTED IN CONNECTICUT
‡ ALSO ADMITTED IN NEW YORK
** ALSO ADMITTED IN DISTRICT OF COLUMBIA

October 31, 2003

John D. Pellegrin, Esq.
9306 Old Keene Mill Road
Burke, VA 22015

Re: Histogenics Corporation v. SRS International, Inc.

Dear Mr. Pellegrin:

As you know, on behalf of my client, Histogenics Corporation, and pursuant to the provisions in the agreement between Histogenics and your client, SRS International, Inc., I submitted the contractual dispute for arbitration and mediation to the Commercial Division of the American Arbitration Association in East Providence, Rhode Island. I made the submission on October 9, 2003. On October 27, 2003, my submission, together with my entry fee, was returned to me without explanation, other than a failure to comply with the "filing requirements". A call to AAA revealed that they will not accept a case unless the contractual arbitration provision specifies AAA as the arbitrator or the parties, by agreement, submit the dispute to AAA for arbitration/mediation.

However, before returning my submission to me, I understand that AAA communicated with you to determine whether SRS International, Inc. would be agreeable to having this dispute arbitrated/mediated by AAA. I was advised that you declined to agree to submission of the dispute to AAA.

I am writing to ask that you, and SRS International, reconsider your position. As you know, AAA is an internationally renowned arbitration/mediation service with impeccable credentials. I can think of no better forum to attempt to resolve this dispute. Please advise as to whether you are willing to reconsider and submit the case to AAA for mediation initially, to be followed by arbitration if it cannot be resolved at mediation.

Sincerely,

L. Jeffrey Meehan

LJM/jmc

201821-1

G

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SRS INTERNATIONAL CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
HISTOGENICS CORP., et. al.	)	**Civil Action No. 1:04cv00141 (RCL)**
	)	
Defendants.	)	
	)	

ORDER

Upon consideration of the parties' written submissions and the relevant law, and in accordance with the memorandum opinion released this date, it hereby is

ORDERED, that defendants' Motion to Dismiss [3] is GRANTED. It hereby further is

ORDERED, that defendant Histogenics Corporation is dismissed as to all Counts pursuant to the Federal Arbitration Act. It hereby further is

ORDERED, that defendants Takagi Industrial, Takagi Sangyo, Takao Takagi, Shuicki Mizuno, Eric Roos, and Toshimasa Tokuno are dismissed as to all Counts for lack of personal jurisdiction. It hereby further is

ORDERED, that individual defendant Laurence J. B. Tarrant is dismissed as to Counts 1 and 7 because of the arbitration clause and, in the alternative, based on a lack of personal jurisdiction, and that defendant Tarrant is dismissed as to Counts 2-6 for lack of personal jurisdiction.

SO ORDERED.

Signed by Royce C. Lamberth, United States District Judge, on August 16, 2004.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SRS INTERNATIONAL CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
HISTOGENICS CORP., et. al.	)	**Civil Action No. 1:04cv00141 (RCL)**
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION

INTRODUCTION

This matter comes before the Court on defendants' motion to dismiss on the basis of the Federal Arbitration Act, Fed. R. Civ. P. 12(b)(2), and Fed. R. Civ. P. 12(b)(6). The motion to dismiss pertains to plaintiff's complaint alleging seven different causes of action against three corporations and five of their employees and officers. Upon consideration of the written submissions of the parties and the relevant law, defendants' motion to dismiss shall be granted.

BACKGROUND

The Parties

SRS International ("the Plaintiff" or "SRS") brings suit for claims related to a contract executed between plaintiff and defendant Histogenics. Plaintiff SRS is a private company incorporated under District of Columbia law, which provides consulting services, data development in regulatory affairs, clinical trials design, and related services in the pharmaceutical, biomedical, and related industries. Compl. ¶ 13. SRS represents clients who

appear before the Federal Drug Administration ("FDA"), the Environmental Protection Agency ("EPA") and other agencies. Id. Plaintiff brings this action against eight defendants.

Defendant Histogenics is a research and development biotechnology company whose mission is to combine technology with tissue engineering expertise to perfect the growing of human tissue outside the body. Compl. Ex. 22. Individual defendant Laurence J.B. Tarrant ("Tarrant") is the President of Histogenics. Individual defendants Eric Roos ("Roos") and Dr. Toshimasa Tokuno ("Tokuno") are both "high level employees/executives of Histogenics" who have been "integrally involved with [the subject matter of this dispute]." See Pl.'s Opp'n. to Defs.' Mot. to Dismiss P 6, 9-10. SRS alleges that, "one or more of them has been instrumental in sabotaging SRS's efforts. . to advise Histogenics." Id. at 10.

Defendant Takagi Industrial Co. ("Takagi Industrial") is Histogenics' "corporate partner and principal investor" with its principal place of business in Japan. Id. at ¶ 6. Defendant Takagi Sangyo ("Takagi Sangyo") is a division of the defendant Takagi Industrial and a firm specializing in the development of computer based machinery. Id. at ¶ 6, Ex. 22. Individual defendant Takao Takagi ("Takagi") is the Executive Director of the personal computer division of Takagi Sangyo. Individual defendant Shuicki Mizuno ("Mizuno") is an employee of Takagi Sangyo.

The Master Agreement and Subsequent Revisions

Defendant Histogenics engaged SRS to assist, consult and guide defendants' to secure FDA approval for a human cell derived neo-cartilage implant ("NeoCart").[1] Id. at ¶ 14. On

[1]For the NeoCart implant to obtain marketing approval in the United States, the defendants would need to conduct pre-clinical development and testing, obtain an Investigation New Drug exemption from the FDA, conduct further clinical trials, and prepare and submit a New Drug Application for review and approval by the FDA. Compl. ¶ 14. If approved, NeoCart would allow doctors to repair cartilage injuries in areas such as the knee by extracting healthy

April 5, 2001, Histogenics and SRS executed a Master Agreement ("Agreement") according to which SRS would represent, advise, and consult with defendant Histogenics on matters related to FDA affairs and strategy, clinical and non-clinical sciences and study design, clinical and non-clinical research management, clinical and non-clinical data development, evaluation, quality assurance, and investigational drug product manufacturing control and product characterization issues.[2] See id. at ¶ 14.

The payment due dates and amounts were amended several times after executing the original Agreement. The initial Task Order, executed on April 5, 2001 by SRS and on April 11, 2001 by Histogenics, set forth the specific nature of the work to be performed by SRS and estimated the total cost and value of the work at $803,295.63 on the multi-year contract. Compl. at ¶ 20.

The first amendment to the initial Task Order, executed October 3, 2001 by SRS and October 7, 2001 by Histogenics, changed the total value to $1,138,824. Id. at ¶ 21. Both parties were in agreement regarding this increase, which was apparently due to changes in the scope of work to be performed. Id. On October 10, 2001, an additional $202,752 was added to the contract value, which was necessitated by a clerical error. Id. at ¶ 23. Histogenics made regular payments according to the October 10, 2001 payment schedule with no question, comment or complaint. Id. at ¶ 24.

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cartilage from a patient with a cartilage injury and implanting it into the damaged area.

[2]Plaintiff presented to the FDA a plan for development of the NeoCart, which was generally agreed to by the FDA, and also negotiated with the FDA on Histogenics' behalf to obtain a significant reduction in the length of the post-implantation follow-up period. Id. at ¶ 12. Plaintiff alleges that, therefore, Histogenics received "the major benefit of its contract with SRS at the start of the contract period." Id.

The next revision concerned not the total value of the contract, but decreased the number of months over which a set amount would be paid. Id. at ¶ 25. Histogenics approved this revision in February 2002, and again made regular payments pursuant thereto with no question, comment or complaint. Id.

On June 4, 2002, there was a fourth payment schedule revision and again, Histogenics made payments against this with no question ,comment or complaint. Id. at ¶ 26. The fifth revision took place on or about November 5, 2002, which involved an $851,290.00 increase in fees to SRS which was concomitant to a program cost reduction of $2,093,531.00 in clinical site costs. The sixth revision occurred on December 5, 2002 and incorporated a revised payment schedule accommodating "Tarrant's/Histogenic's" request to "further shift a portion of the SRS cost/compensation increases . . . to the later stages [of clinical development]." Id. at ¶ 28.

The seventh revision occurred on January 13, 2003 and involved "Tarrant's/Histogenic's" second request to "shift additional amounts of its charges." Id. at ¶ 29. This particular proposed schedule was approved and agreed to by Histogenics. Id. Histogenics continued to make regular payments on the latest payment schedule through July 2003 with no question, comment, or complaint. Id.

The "Material Breach"

On or about August, 2003, SRS and Histogenics had a meeting scheduled to discuss ways to accommodate Histogenics' latest (third) request to modify the payment schedule. Id. at ¶ 30. The meeting was abruptly cancelled by Histogenics with no reason or re-schedule date given by Histogenics. Id. Plaintiff alleges that, "with no warning, Histogenics claimed a 'material breach' by SRS of the Master Agreement and subsidiary derivative Task Orders and has, since that time,

refused to honor the Master Agreement and the payment schedules associated with it and the Task Orders there under." Id. at ¶ 40. This alleged breach and other related actions form the basis for plaintiff's claim.

Histogenics, however, has a rather different presentation of the facts. Histogenics claims that after SRS accomplished the first few tasks stipulated in the Agreement, "SRS's performance rapidly declined." Defs.' Mot. to Dismiss P 6. Furthermore, Histogenics states that a clinical study of the NeoCart implant was supposed to be completed by September 2002, but by August 2003, not a single patient had been enrolled in the study. Id. Finally, Histogenics states that it was "receiving no benefit for the thousands of dollars in unexplained 'consulting' fees that it was paying to SRS every month" and subsequently notified SRS that it was terminating the Agreement pursuant to the contract's termination clause. Id.

Yet, plaintiff declares that Histogenics' failure to recruit patients was not caused by SRS's failure to perform. Rather, SRS alleges that it was caused by the inadequacy of clinical investigation site selection by Histogenics, which was conducted contrary to SRS's recommendations. Id. at ¶ 13. Plaintiff states that Histogenics did not terminate SRS's contract on the basis of a failure in performance, but rather, on the basis of an alleged "material breach" by SRS. Plaintiff contends that the reason for defendants' claim of "material breach" is the addition of $202,752.00 to the program budget, and subsequent budget amendments, all of which had been approved by Histogenics and routinely paid without objection for some 22 months. Id. at ¶ 17.